201-14566

NCIC HPV
Sent by: Mary-Beth Weaver

06/25/2003 01:34 PM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on 3 and 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde, CAS# 31906-04-4

Richard_Denison@environmentaldefense.org on 06/25/2003 10:14:24 AM

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cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on 3 and 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde, CAS# 31906-04-4

(Submitted via Internet 6/25/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, Edwin.L.Mongan-1@usa.dupont.com, and Rauckman@toxicsolutions.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 3 and 4-(4-hydroxy-4-methylpentyl) -3-cyclohexene-1-carboxaldehyde, CAS# 31906-04-4.

The Flavor and Fragrance High Production Volume Consortia have submitted a generally well-organized and well-written Robust Summary/Test Plan for 3 and 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde (HMPCC). Little or no information is provided that addresses the level of production, transport or uses of HMPCC. Although these kinds of use and exposure-related data are not required by the HPV Program, they are helpful in assessing adequacy of data and they are also informative to the public.

The Test Plan provides a good description of data describing the fate and toxicity of chemicals having close structural relationships to HMPCC and effectively bridges appropriate data from these studies to predict the fate of HMPCC. Our review of data indicates structurally related compounds are readily absorbed from the gastrointestinal tract, rapidly metabolized and excreted and have low toxicity and short half-lives in test animals.

Experimental data for HMPCC are apparently very limited. Thus, chemical-physical data and data on environmental fate and ecotoxicity required to meet the respective SIDS elements have been calculated and/or bridged from data generated for structurally similar chemicals. Our review of summaries of these studies indicates they are generally appropriate. Nevertheless, the Test Plan proposes additional tests to determine values for most of these parameters specific to HMPCC. We feel this proposal represents a very responsible and preferable approach.

Data addressing mammalian toxicity of HMPCC are also limited, but they are sufficient to confirm that this chemical has low to moderate acute toxicity and is not a mutagen. It has not been the subject of repeated or chronic dose studies. Structurally related chemicals have been the subjects of such studies and have been shown to have low to moderate toxicity. Thus, we approve of the proposal to bridge those data to address the SIDS element for repeated dose testing. We would also point out that repeated dose toxicity data will be generated through the reproductive/developmental toxicity screening assay using the OECD 421 Guideline that has been proposed by the sponsor. We feel the latter studies are especially

appropriate because of the widespread use of HMPCC in consumer products.

Minor Comments:
1. Test Plan, page 14: The first paragraph describes oral LC50s. We think the sponsor intended LD50s.
2. Test Plan, page 14: The second paragraph states "Exposure to statistically generated saturated vapor ...". What does this mean?
3. Test Plan, page 14: Second paragraph: Our review of the Robust Summary indicates that contamination with acrolein compromised this study to the point that it should probably not be cited in this report. However, if it is cited, the concentration of acrolein, 42 ppm, should be mentioned in the Test Plan as well.
4. Robust Summary, page 29: The dose is not given for this inhalation study.

Thank you for this opportunity to comment.

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